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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,103	06/05/2001	Herman F. Staats	180/102/2	6817
25297	7590	07/13/2004		
JENKINS & WILSON, PA 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707				
			EXAMINER LANDSMAN, ROBERT S	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/874,103	STAATS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert Landsman	1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 64-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64,72-76 and 80-84 is/are allowed.
- 6) ☒ Claim(s) 65-71 and 77-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Amendment dated 6/17/04 has been entered into the record.
- B. Claims 64-84 are pending in this application and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Claim Rejections - 35 USC § 103***

- A. All rejections under 35 USC 103 have been withdrawn in view of Applicants' arguments that Elson's teachings are limited to the assertions that living pathogens are capable of invading and/or causing disease at mucosal surfaces and that mucosal administration can induce both systematic and mucosal immune responses against such pathogens. Thus, Elson does not provide any suggestion that intramucosal administration of antigen-adjuvant compositions will give rise to an immune response.

Furthermore, Elson specifically teach away from the instant invention by stating "most protein antigens are not only poor immunogens when given mucosally, but induce tolerance instead of immunity. Thus, irrespective of the ease of mucosal administration, Elson suggests that intramucosal administration with protein antigens would be expected to induce tolerance, instead of eliciting an immune response. It should be brought to Applicants' attention, however, that the present claims are not limited to protein antigens.

### ***3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. Claims 65-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using the cytokines IL-1 $\beta$ , IL-12, IL-15, IL-18 and combinations thereof, does not reasonably provide enablement for methods using "at least one other cytokine." The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicants have only provided guidance and working examples of the use of IL-1 $\beta$ , IL-12, IL-15, IL-18 alone and in combination. Applicants have not provided any guidance or working examples of the use of these cytokines with any other cytokines. The enablement rejection is being made in view of Applicants' arguments on page 9 of the Response dated 6/17/04. Applicants argue, under 35 USC 103, the Examiner's rejection which states that "it would be expected that if IL-1 $\beta$  is effective in the method of Gao, then any other interleukin would also be effective." In their argument, Applicants submit that this assertion is not supported by any scientific evidence, nor by any teachings in the cited combination. Given Applicants' own statement that it would not be expected that any other interleukin (i.e. cytokine) would be effective, it would, therefore, not be predictable to the artisan what other cytokines could be used in the claimed methods.

#### ***4. Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 77-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The method steps are identical. It is not understood, given the presently recited steps, how administering an antigen/adjuvant composition intramucosally can result in a systemic, mucosal and cell-mediated response. In other words, it is not clear how the administration of the compound, without an alteration of method steps, would result in each one of these situations separately. Given the recited steps, it appears that all of these responses would occur simultaneously. Therefore, there is no difference in the method steps of claim 77-79.

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**5. Conclusion**

A. Claims 64, 72-76 and 80-84 are allowable.

***Advisory information***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
July 12, 2004

  
**ROBERT LANDSMAN**  
**PATENT EXAMINER**